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Changes in drinking behavior among evacuees after the Fukushima Daiichi Nuclear Power Plant accident : the Fukushima Health Management Survey

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Abstract

Introduction Traumatic experiences and disordered sleep are strongly associated with drinking problems. We examined the effects of experiencing the Great East Japan Earthquake and subsequent nuclear power plant accident, and of sleep problems, on behavioral changes observed in non-drinkers.

Methods This study examined cross-sectional data from the Mental Health and Lifestyle Survey conducted among residents in restricted areas of Fukushima in 2012. Participants were 21,454 evacuees aged 20 years or older at the time of disaster. People who did not drink before the disaster but became drinkers afterwards were compared with the rest of the cohort. We analyzed the association between behavioral changes in non-drinkers and potentially predictive variables, using logistic regression.

Results The behavioral change of non-drinkers becoming drinkers ($n=2,148$) was significantly related to being male (OR=1.93, 95% CI : 1.74-2.15), being younger (21-49 yrs, OR=1.85, 95% CI : 1.60-2.13), having less educational attainment (up to high school graduate, OR=1.21, 95% CI : 1.09-1.35), smoking (OR=1.22, 95% CI : 1.08-1.38), losing family or relatives (OR=1.21, 95% CI : 1.07-1.37), change in employment (OR=1.19, 95% CI : 1.07-1.32), having severe sleep problems as measured by a Japanese version of the Athens Insomnia Scale (3-8, OR=1.45, 95% CI : 1.30-1.62), and severity of traumatic symptoms as measured by the PTSD Checklist Stressor-Specific (PCL-S) score (<44 , OR=1.33, 95% CI : 1.17-1.51).

Conclusion Having sleep problems and having more severe traumatic symptoms are significantly related to non-drinkers becoming drinkers.

Key words : disaster, alcohol, trauma, sleep

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Introduction

The Great East Japan Earthquake that occurred on March 11, 2011 caused a tsunami and an accident at the Fukushima Daiichi Nuclear Power Plant (hereinafter NPP). As evident from what happened in Chernobyl, there were great concerns about long-term psychological trauma among those who survived evacuation, arising from : fears about radiation exposure ; loss of family, relatives, and/or property ; and experience of other threats to life and livelihood.

Many studies have shown that disasters can have a significant impact on mental health. Experience of disaster could cause post-disaster mental distress among victims, including depression, post-traumatic stress disorder (PTSD), and suicidality^{1,2)}. Many victims showed increased symptoms of stress, difficulties caused by anxiety and sleep disturbance, and depressive symptoms or hopelessness after the Hanshin-Awaji Earthquake³⁾. Disasters are experienced by many people and may result in a wide range of mental and physical health consequences⁴⁾. Depression and anxiety are also commonly observed psychological problems in both natural disasters and terrorist attacks^{5,6)}. Severe psychological distress was likely to be found among those who experienced the earthquake, tsunami, and subsequent nuclear power plant accident⁷⁾.

Associations between natural disasters and the use and abuse of alcohol are well established⁸⁾. It can be imagined that people who have experienced a disaster consume alcohol to soothe their anxiety and help them fall asleep. Beaudoin reported that exposure to traumatic events increased alcohol consumption among evacuees after Hurricane Katrina⁹⁾. Similarly, Cerda *et al.* found increased alcohol consumption after a disaster when compared with pre-disaster levels of consumption¹⁰⁾. Keyes and Hatzembuehler reviewed epidemiological studies and reported that escalation of alcohol use after a disaster may be most noticeable among those who already manifested drinking problems before the disaster¹¹⁾. Flory *et al.* described that survivors of Hurricane Katrina experienced alcohol consumption-related problems at a higher rate than expected as compared to pre-disaster prevalence data¹²⁾. North *et al.* reviewed 10 disaster studies and recognized that while the post-disaster prevalence of alcohol use disorders was 19%, only 0.3% of the sample developed an acute new post-disaster alcohol use disorder, but they did not further discuss the profile of those who developed new alcohol use disorder¹³⁾. Brower *et al.* pointed out that alcohol was

also used as a way to deal with sleep problems among those with alcohol dependence¹⁴⁾. Zhabenko discussed a correlation of alcohol dependence and insomnia among Polish patients using the Athens Insomnia Scale¹⁵⁾.

In this context, the development of a drinking habit after a disaster could provoke mental health problems. For instance, Volpicelli *et al.* discussed a hypothesis that alcohol may relieve PTSD symptoms, such as anxiety, irritability, and depression because drinking compensates for deficiencies in endorphin activity following a traumatic experience¹⁶⁾. In addition, a study conducted in the same population as this study revealed that changes of drinking style rather than level of individual consumption could significantly affect mental health conditions among affected people¹⁷⁾. However, research has not yet fully explored whether disasters influence people who were non-drinkers before a disaster to become drinkers afterwards.

It seems highly likely that drinking behaviors would be considerably affected among those who have experienced a disaster, subsequent evacuation, and consequent suffering from traumatic stress reactions and sleep problems. A literature review showed that previous studies focused on those with preexisting alcohol problems and their other problems after a disaster^{8-12,14)}. However, the relationship between change in drinking behavior and disaster-related experience among those who did not drink before the disaster has not yet been examined.

After the Fukushima NPP accident, Fukushima Prefecture launched the Fukushima Health Management Survey, an extensive health survey to monitor the health status of evacuees and to arrange for those who are at risk of health problems to liaise with local resources¹⁸⁾. Using baseline data from this survey, this study aimed to examine the relationship between changes in drinking behavior with sleep problems and traumatic symptoms, while controlling for disaster related-factors. The research question examined in this study was : What are the predictors of becoming a drinker ?

Methods

Study design

This study was a part of a longitudinal survey to monitor the mental health status of evacuees of the Fukushima NPP accident^{18,19)}. We used data from the Fukushima Health Management Survey, specifically, cross-sectional data from its Mental Health

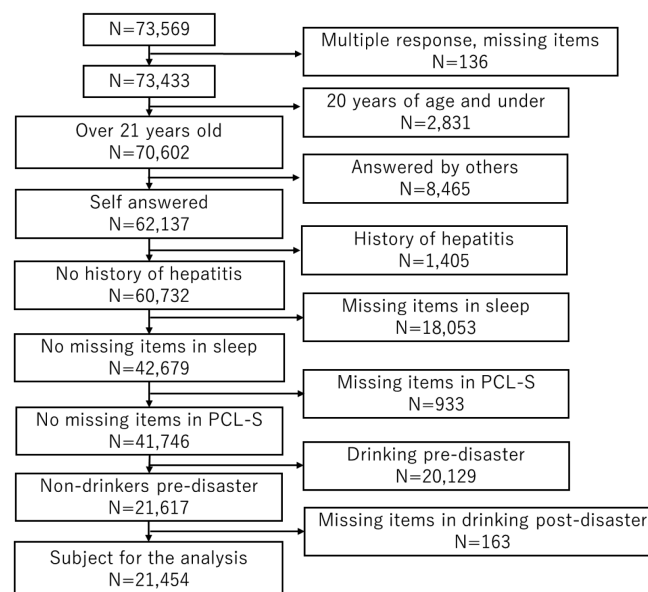


Figure 1

and Lifestyle Survey conducted in 2012, about one year after the accident.

This study was approved by the ethics review committee of Fukushima Medical University, which is guided by local policy, national law, and the World Medical Association Declaration of Helsinki.

Participants

The target population of this survey was the entire population in the evacuation zone designated by Fukushima Prefecture due to the NPP accident (210,189 people). The survey items varied according to participants' age range, with those who were 16 years or older at the time of the questionnaire using a self-administered PTSD Checklist Stressor-Specific Version (PCL-S)¹⁸⁾. Hence, those who were aged 15 years or older as of March 11, 2011, ($n=180,604$) were the intended subjects of this study, and data on 73,569 participants were analyzed based on their valid responses (response rate : 40.7%)²⁰⁾.

In Japan, the legal drinking age is 20 years ; therefore, we decided to exclude those aged less than 20 years at the time of the disaster. In order to do so, we excluded those who were aged less than 21 years at the time of the survey, which took place a year after the disaster. We also excluded those whose questionnaires were administered by others, those who had a history of chronic hepatitis, and those with missing items pertaining to sleep and PCL-S scores, so that the final sample size was $n=21,454$ (Figure 1).

We divided the participants into three age

groups, 21 to 49 years, 50 to 64 years, and 65 years and older, according to the previous study by Ueda *et al.* in which we had analyzed the same subjects¹⁷⁾.

Measurements

Changes in drinking behavior

We asked about drinking patterns before the disaster by inquiring whether they used to drink less than once a month, and at the time when the questionnaire was administered by asking the average frequency and amount of alcohol consumed, and divided subjects into two groups : those who had been non-drinkers before the disaster and became drinkers post-disaster (hereinafter new drinkers), and those who had been non-drinkers before the disaster and remained non-drinkers post-disaster.

Those who had been diagnosed with chronic hepatitis were excluded from the data set since their alcohol consumption would be affected by their medical treatment.

Socioeconomic and other factors

For demographic and other variables, items were codified and examined as follows :

1) Socioeconomic variables included educational attainment : elementary school, junior high school, and high school as 0 ; vocational college, junior college, university (4 years), and graduate school as 1. This was in accord with a previous study by Ueda *et al.*, in which we had analyzed the same subjects¹⁷⁾ for analytical purposes. 2) Other

factors included : subjective health status as very good, good, normal, poor, or very poor ; smoking as yes or no ; and exercise habits as almost every day, 2 to 4 times a week, once a week, or almost never.

Experience of disaster

Experience of disaster pertained to items that characterized the nature of disaster exposure, since individual experience differed significantly depending on where the person experienced disaster. Items describing exposure to the disaster included : experience of the tsunami as yes or no ; and experience of the NPP accident – defined as hearing an explosion – as yes or no.

Disaster-related problems

Items describing secondary life stressors induced by the disaster included : experiencing damage to one's house as yes for partial collapse, extensive collapse, or total collapse ; and no for damage or partial damage ; loss of family or relatives because of the disaster as yes or no ; change in employment as yes or no ; and change in living arrangements as 0 for a rental home, apartment, relative's home, one's own home or other ; and 1 for evacuation shelter or temporary housing.

Sleep problems

A Japanese version of the Athens Insomnia Scale (AIS) was previously developed and validated²¹⁾, and we used a simplified Japanese AIS, for which its psychometric properties were recently investigated for acceptable reliability (Cronbach alpha was 0.81)²²⁾. We asked eight questions regarding sleep problems, just as in the original AIS. In terms of satisfaction with sleep over the past month, we assigned 0 to "satisfied" and "slightly dissatisfied," and 1 to "quite dissatisfied" and "very dissatisfied or have not slept at all." For the other seven questions regarding experiences with sleep, we codified frequency of the problems as at least three times a week, instead of the original 4-point Likert scale (taking time to fall asleep, waking up in the middle of the night, waking up earlier than planned, not getting enough sleep, feeling depressed during the day, having reduced mental and physical activity, and feeling tired during the day). We allocated 1 to "yes," and tallied the number of sleep problems.

Traumatic symptoms

Traumatic symptoms were assessed using the PTSD Checklist Stressor-Specific (PCL-S) scale. In the PCL-S scale, participants were asked to describe

their experiences, in the past month, related to the earthquake and the subsequent power plant accident. Each question was rated on a 5-point Likert scale from one (not at all) to five (very much), with higher scores signifying more severe traumatic symptoms (range : 17–85). The original PCL was described by Blanchard, EB *et al.* in 1996²³⁾ and very recently, the reliability of a Japanese version was tested by Suzuki²⁴⁾, for the same population, which showed sufficient reliability (Cronbach's Alpha was 0.92). In this study, we used the same cut-off threshold as the previous study¹⁷⁾.

Statistical analysis

In order to explore the characteristics of new drinkers, we compared their basic characteristics and changes in drinking behavior using the chi-square test (Table 1). Disaster-related and socioeconomic variables were also compared between new drinkers and non-drinkers before and after the disaster using the chi-square test.

We performed a logistic regression analysis adjusting for age and gender, then calculated adjusted odds ratios and 95% confidence intervals (CIs) using multiple logistic regression analyses by entering factors which were statistically significant in single logistic regression analysis (Table 2). These were performed to examine the association of changes in drinking behavior pre- and post-disaster with the following factors : basic characteristics and socioeconomic status, that is, educational attainment, subjective health status, smoking, and exercise habits ; the experience of disaster, that is, experience of the tsunami, experience of the NPP accident ; disaster related problems, that is, house damage, loss of family or relatives, changes in employment, and changes in living arrangements ; sleep problems, using the total number of self-reported problems related to sleep (0 to 2 and 3 to 8) for exploratory effort, but not to see dose response, as a dependent variable ; and traumatic symptoms, using the range of PCL-S ≥ 44 as a dependent variable. Significance was set at $p < 0.05$.

All statistical analyses were conducted using SPSS version 21.0.

Results

Table 1 shows the characteristics of new drinkers. The number of new drinkers was 2,148 (male : 880, female : 1,268), out of 21,454 (male : 5,943, female : 15,511) participants. The proportion of

Table 1. Characteristics of the non-drinkers and the new drinkers ($n=21,617$)

	Total		Non-drinkers		New drinkers		χ^2	df	P values
	n	%	n	%	n	%			
Gender	$n=21,454$		$n=19,306$		$n=2,148$				
Males	5,943	27.7	5,063	26.2	880	41.0	209.788	1	<0.001
Age	$n=21,454$		$n=19,306$		$n=2,148$				
21-49 years old	8,861	41.3	7,701	39.9	1,160	54.0	170.374	2	<0.001
50-64 years old	6,652	31.0	6,073	31.5	579	27.0			
65 years old and older	5,941	27.7	5,532	28.7	409	19.0			
Socioeconomic and other factors									
Education attainment	$n=20,923$		$n=18,814$		$n=2,109$				
Primary or middle school, or high school	14,946	71.4	13,547	72.0	1,399	66.3	29.879	1	<0.001
Vocational college, junior college, university, or graduate school	5,977	28.6	5,267	28.0	710	33.7			
Subjective health status	$n=21,139$		$n=19,021$		$n=2,118$				
Very good, good, or normal	17,349	82.1	15,629	82.2	1,720	81.2	1.190	1	0.275
Poor, or very poor	3,790	17.9	3,392	17.8	398	18.8			
Smoking	$n=21,247$		$n=19,126$		$n=2,121$				
Current smoker	3,531	16.6	2,997	15.7	534	25.2	124.534	1	<0.001
Exercise habit	$n=21,234$		$n=19,108$		$n=2,126$				
Almost everyday	2,729	12.9	2,492	13.0	237	11.1	24.055	3	<0.001
2 to 4 times a week	3,933	18.5	3,600	18.8	333	15.7			
1 a week	2,763	13.0	2,483	13.0	280	13.2			
Almost never	11,809	55.6	10,533	55.1	1,276	60.0			
Experience of disaster									
Experience of tsunami	$n=21,454$		$n=19,306$		$n=2,148$				
Yes	3,836	17.9	3,379	17.5	457	21.3	18.743	1	<0.001
Experience of nuclear power plant accident	$n=21,454$		$n=19,306$		$n=2,148$				
Yes	10,802	50.3	9,651	50.0	1,151	53.6	9.994	1	0.002
Disaster related problems									
House damage									
Partial-collapse and severer	$n=20,114$		$n=18,123$		$n=1,991$				
Yes	3,048	15.2	2,717	15.0	331	16.6	3.720	1	0.054
Loss of family or relatives	$n=21,170$		$n=19,056$		$n=2,114$				
Yes	4,045	19.1	3,575	18.8	470	22.2	14.843	1	<0.001
Change in work	$n=20,553$		$n=18,454$		$n=2,099$				
Yes	10,985	53.4	9,693	52.5	1,292	61.6	61.735	1	<0.001
Living arrangement	$n=17,376$		$n=15,693$		$n=1,683$				
Rental housing, apartment, relative's home, own home or other	15,259	87.8	13,765	87.7	1,494	88.8	1.584	1	0.208
Evacuation shelter or temporary housing	2,117	12.2	1,928	12.3	189	11.2			
Psychiatric problems									
Sleep problem	$n=21,454$		$n=19,306$		$n=2,148$				
0	3,821	17.8	3,526	18.3	295	13.7	96.841	8	<0.001
1	3,082	14.4	2,826	14.6	256	11.9			
2	3,006	14.0	2,755	14.3	251	11.7			
3	2,776	12.9	2,505	13.0	271	12.6			
4	2,414	11.3	2,137	11.1	277	12.9			
5	2,028	9.5	1,786	9.3	242	11.3			
6	1,624	7.6	1,417	7.3	207	9.6			
7	1,427	6.7	1,255	6.5	172	8.0			
8	1,276	5.9	1,099	5.7	177	8.2			
Traumatic symptoms (PCL) ≥ 44	$n=21,454$		$n=19,306$		$n=2,148$				
Yes	4,610	21.5	4,025	20.8	585	27.2	46.728	1	<0.001

those who became new drinkers was higher among males, in the younger age group, in those with less educational attainment, in smokers, in those less likely to exercise, in those who had experienced the tsunami and NPP accident, in those who experienced more family loss and changes in employment, and in those with accumulated sleep problems and higher PCL-S scores. Pearson's chi-square test was performed to test statistical significance.

Table 2 shows the results of a comparison between new drinkers and non-drinkers using a logistic regression analysis to examine the relationship

between changes in drinking behavior with sleep problems and traumatic symptoms. We controlled for basic characteristics, i.e., age and gender, disaster-related variables, and socioeconomic and other factors. New drinkers had a significantly higher rate of sleep problems. The OR of severe sleep problems was 1.45 (95% CI: 1.30-1.62).

The behavioral change of becoming a new drinker was also significantly correlated with traumatic symptoms, and the OR of traumatic symptoms according to the PCL-S score of 44 and over was 1.33 (95% CI: 1.17-1.51). Furthermore, we ob-

Table 2. The associations between potentially predictive variables and starting drinking

Model	Statement drinking status before and after disaster (Sex-Age adjusted model)			Statement drinking status before and after disaster (multivariable analysis)		
	New drinker			New drinker		
	OR	(95%CI)	P value	OR	(95%CI)	P value
<i>n</i> =21,454						
Gender (0 Females, 1 Males)						
Males				1.93	1.74-2.15	<0.001
Age (0 65 years old and older)						
21-49 years old				1.85	1.60-2.13	0.003
50-64 years old				1.24	1.07-1.44	0.004
Socioeconomic and other factors						
Education attainment (0 less High school, 1 more Vocational college/Junior college)	1.17	1.06-1.29	0.002	1.21	1.09-1.35	0.001
Subjective health status (0 Very good/Good/Normal, 1 Bad/Very bad)	1.17	1.04-1.32	0.009	0.90	0.78-1.03	0.135
Smoking (0 Never smoked/Quit, 1 Current smoker)	1.23	1.10-1.38	<0.001	1.22	1.08-1.38	0.002
Exercise habit (0 Almost never, 1 Once a week/2-4 times a week/Almost every day)	1.02	0.97-1.06	0.503			
Experience of disaster						
Experience of tsunami (0 No, 1 Yes)	1.25	1.12-1.40	<0.001	1.06	0.93-1.21	0.357
Experience of nuclear power plant accident (0 No, 1 Yes)	1.21	1.11-1.33	<0.001	1.03	0.93-1.14	0.590
Disaster related problems						
House damage (0 No damage/Partial damage, 1 Partial collapse and severer)	1.18	1.04-1.34	0.011	1.02	0.88-1.17	0.822
Loss of family or relatives (0 No, 1 Yes)	1.32	1.18-1.47	<0.001	1.21	1.07-1.37	0.002
Change in work (0 No, 1 Yes)	1.33	1.21-1.46	<0.001	1.19	1.07-1.32	0.001
Living arrangement (0 Rental housing/Apartment/Relative's home/Own home/other, 1 Evacuation shelter/Temporary housing)	0.93	0.79-1.09	0.338			
Psychiatric problems						
Sleep problem (0 0-2)						
3-8	1.60	1.46-1.76	<0.001	1.45	1.30-1.62	<0.001
Traumatic symptoms(PCL-S) ≥ 44 (0 No, 1 Yes)	1.57	1.42-1.74	<0.001	1.33	1.17-1.51	<0.001

tained sufficient internal consistency in the PCL-S score ; Cronbach's alpha was 0.95.

The results showed that age and gender groups were significantly associated with behavioral change in drinking behavior as well as with psychological distress. The OR of being male was 1.93 (95% confidence interval, CI : 1.74-2.15), and compared with those aged over 65 years, the OR of those aged between 21 and 49 years was 1.85 (95% CI : 1.60-2.13) for the change from non-drinking to drinking. In socioeconomic and other factors, having less educational attainment (OR=1.21, 95% CI : 1.09-1.35) and having a smoking habit (OR=1.22, 95% CI : 1.08-1.38) were statistically significant, but subjective health status did not show significant correlations. Among experience of disaster and related factors, loss of family or relatives (OR=1.21, 95% CI : 1.07-1.37) and change in employment (OR=1.19, 95% CI : 1.07-1.32) increased the likelihood of becoming a new drinker. On the other hand, experience of the tsunami, experience of the NPP accident, and house damage did not have significant correlations with the change in drinking behavior.

Discussion

Similar to other studies^{25,26)}, male and younger respondents were more likely to become new drinkers. The results show that young males might have developed inadequate coping skills in response to disaster. In addition, logistic regression analysis revealed that the respondents who did not drink pre-disaster were likely to become new drinkers post-disaster if they had more sleep problems and more severe traumatic symptoms. Those who did not have a drinking habit before the disaster may have begun consuming alcohol to cope with their psychological reactions, such as sleep difficulties or traumatic symptoms. Previous studies show that traumatic experiences and other stressors could lead to higher levels of alcohol consumption⁹⁻¹²⁾ and, furthermore, sleep difficulties are often identified as a significant risk for problematic drinking^{14,15)}. The present study also revealed that those who had high traumatic responses and/or sleep difficulties were considered to be vulnerable to alcohol misuse, consistent with findings obtained from past studies. Considering that posttraumatic stress responses are more likely to cause sleep difficulties – including nightmares relating to traumatic events – in order to prevent affected people from starting or restarting problem drinking after a disaster, we firstly need to provide adequate care and psychoeducation for those

experiencing traumatic events during disasters.

As is well known, habitual drinking generally contributes to physical illnesses (e.g., diabetes, hypertension, and alcoholic hepatitis) and other mental health issues (e.g., depression, dementia, violence, and suicide)²⁷⁾. In Fukushima Prefecture, the standardized suicide mortality ratio decreased in the first two years after the disaster but increased in the third year after the disaster²⁸⁾ and the number of disaster-related suicide cases was remarkably larger than that in other areas affected mainly by the tsunami, such as coastal Miyagi and Iwate Prefectures²⁹⁾. Evidently, urgent countermeasures to prevent suicide are needed in Fukushima³⁰⁾. Given the significant relationship between suicide and alcohol abuse²⁷⁾, discouraging people from heavy drinking habits can be highly beneficial, especially for the prevention of suicide.

In addition, this study showed that smoking was significantly associated with starting drinking. In previous studies, being a male, being younger, having less educational attainment, changing jobs, and having traumatic symptoms were significantly associated with starting smoking³¹⁾. Both studies show that those who begin addictive behavior, i.e., drinking and smoking, share very similar characteristics.

As described above, becoming a new drinker was correlated with age and gender, and younger males may be prone to developing new, yet ineffective, coping strategies, such as heavy drinking, to face their difficulties. Introducing preventive approaches through medical professionals for this potentially high-risk group can be challenging, since they do not develop physical illnesses requiring medical attention or take health check-ups to the extent of older cohorts³²⁾. A study revealed that young people are especially vulnerable to alcohol marketing³³⁾. Therefore, collaborative efforts with the media and alcohol industry, involving various types of educators, could complement other measures to approach this group effectively.

Limitations

This study has several limitations. First, it is critical to point out that this study only assessed drinking status pre-disaster by inquiring about drinking patterns prior to disaster ; therefore, this survey did not allow us to distinguish between those who experienced post-disaster relapses following previously remitted disorders from those who did not have a drinking habit pre-disaster or those who were continuing to drink heavily. Secondly, as this

study employed a cross-sectional design, it limited the identification of risk factors and clarification of causality. Thirdly, the representativeness of the study could be limited since only about 40% of the study population responded to this survey, and thus, a significant number of evacuees did not participate. Lastly, owing to exclusion criteria, more than 20% of the potential sample size was lost to missing data, and we need to acknowledge the level of incompleteness when interpreting results.

Conclusion

According to the present results, newly developed problem drinking was related to accumulated sleep problems and more severe traumatic symptoms. Experiences of disaster, except loss of family or relatives and changing jobs, were not significantly related to the problem. The relationships of sleep problems, traumatic symptoms, disaster experiences, and changes in drinking behavior have been quite well researched. However, there has been no previous study on new drinkers. With its large sample size, this survey enabled us to analyze the behavioral change that occurred in those who had recently become problematic drinkers and to examine how this was associated with other factors.

Prospective longitudinal research is strongly needed to monitor behavioral changes over a longer period to establish causality among factors such as problem drinking and sleep problems.

Conflict of Interest : None declared.

List of abbreviations

AIS : Athens Insomnia Scale

NPP : The Fukushima Daiichi Nuclear Power Plant

PCL-S : PTSD Checklist - Specific

Declaration

Ethics approval and consent to participate :

This study was approved by the ethics review committee of Fukushima Medical University on September 15th, 2015. The approval number is 1316. Informed consent was documented in writing upon entry in the study.

Consent to publish :

Not applicable.

Availability of data and materials :

Data that support the findings of this study are available from Fukushima Prefecture but restrictions apply to its access ; our use was granted specifically for the current study, beyond which the data are not publicly available, but access may be granted from the authors upon reasonable request and with permission of Fukushima Prefecture.

Competing interests :

None declared.

Funding :

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Authors' Contributions :

AY made substantial contributions to the conception, clinical interpretation of results, and manuscript writing. MM and YS made substantial contributions to the conception, clinical interpretation of results, and manuscript writing. HY, SY, SN, TO, AO, HM, MH, HN and MA made substantial contributions to study design, clinical interpretation of results and study conduct. All authors read and approved the final manuscript.

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